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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,991	07/26/2001	John Paul McGee	JANS-0008	7988

7590 03/08/2004

EXAMINER	
FUBARA, BLESSING M	

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ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,991	MCGEE ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-15 and 17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-15 and 17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and request for continued examination under 37 CFR 1.114 filed 12/03/03. Claims 2-15 and 17-29 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 12/03/03 has been entered.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 23-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A mere arrangement or words on a piece of paper or on television screen that is latter printed is non statutory. See *In re Miller*, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); *Ex parte Gwinn*, 112 USPQ 439 (BD. App. 1955); and *In re Jones*, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-15 and 17-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claim 10, the term "other " renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "other"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claims 19 and 23 depend from cancelled claim 1.

The use of parenthetical "(avoiding)" in line 2 of claim 27 is unclear. Applicants may insert ---or--- after "reducing" in claim 27, line 2; delete the opening and closing parenthesis in claim 27, line 2.

The use of "HPMC 2910 5 mPa.s." in claims 6 and 7 is unclear. Clarification is required. Claims 6 and 7 are interpreted as formulations that contain hydroxypropyl methylcellulose (HPMC).

Claims 9 and 15 refer to literature citations and claims must stand on their own to define the invention. See Ex parte Fressola, 27 USPQ2d 1608, 1609. Parenthesis may not be used in the context in which they are used in the claims.

Claim Objections

7. Claims 15, 17-19, 21 and 22 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Claims 15,

17 and 18 do not refer back in the alternative. Claim 19 refers to two sets of claims and depends on a multiple dependent claim. Correction is respectfully requested.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2-6, 10, 17, 22, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. (CA 1326632).

Davis discloses tablet or capsule formulation comprising particles of galanthamine (galantamine) or galanthamine hydrobromide or salt thereof; the particles are coated are coated with pharmaceutically acceptable substance that is soluble in the intestinal tract (abstract and claims 1-4) and the particles are sieved and mixed with excipients selected from the group consisting of hydroxypropyl methylcellulose , ethyl cellulose, starch, silicon dioxide, magnesium stearate and polyethylene glycol (page 3, paragraph 6). Davis discloses that the thickness of the coating on the particles essentially differs from particle to particle and the distribution of the coating thickness is such as to ensure the release of drug particles at different rates (claim 1).

Davis discloses the galanthamine formulation as a long-acting formulation for treatment of Alzheimer's disease and related dementias (paragraph 1 of page 3) and 10-200 mg per day dose is disclosed (paragraph 1 of page 4). The treatment method of the instant claim comprises administering the formulation of instant claim 10 to a human. While Davis is silent on human subject, administering galanthamine formulation is implied in the disclosure. A 1:1

ratio of galanthamine to hydrobromide is implied in the galanthamine hydrobromide salt. Polyvinylpyrrolidone is a film-forming polymer. The viscosity recited in the instant claim is inherent to the galanthamine formulation of Davis. The disclosure of Davis meets the limitations of the claims.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 7, 24, 25, 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (CA 1326632) in view of Davis (US 4, 663,318).

Davis discloses the instant galanthamine formulation. Although administration of the galanthamine formulation is implied in the disclosure of the prior art, Davis fails specifically teach administering the formulation to a patient in need thereof. Nonetheless, Davis discloses administering galanthamine to a subject in need thereof to treat Alzheimer and related diseases (claim 1). Regarding claim 7, one of skill or ordinary skill in the art would know routine experimental easy of formulating a galanthamine formulation where the amount of the active agent to the polymer such that the formulation meets releases the active agent for the treatment of the disease condition. Regarding claims 24 and 25, it is within the purview of the skilled artisan or the person of ordinary skill to formulate different dosages for the effective treatment of the disease condition. And where the general conditions of a claim are disclosed by the prior art, it is not inventive to discover optimum workable ranges by routine experimentation. The conditions recited in instant claim 28 are conditions that are related to Alzheimer's disease and the formulation of the prior art would be expected to be effective against those conditions. The

adverse effects recited in instant claim 29 are inherent effects associated with acetyl cholinesterase inhibitors.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a galanthamine formulation according to the teachings of Davis. One having ordinary skill in the art would have been motivated to administer the galanthamine formulation of Davis to a subject in need thereof according to the teaching of Davis, and specifically to a human subject with the expectation of treating a human subject suffering from Alzheimer's.

12. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600